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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,424	01/22/2001	Sara L. Zaknoen	OC01121K	9553

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1642

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22

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 22

Application Number: 09/767,424
Filing Date: January 22, 2001
Appellant(s): ZAKNOEN, SARA L.

William Lee
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/25/03.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-22 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

6,180,096

KLINE

1-2001

WO 95/13090 GILBERT et al, (May 18, 1995)

WO 97/12630, DUGAN et al (April 10, 1997)

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/12630 in view of Ragab US 6346524 (priority to 3/30/99) and Kline US 6180096 (which has priority to 3/26/98) or WO 95/13090.

WO 97/12630 discloses the combination therapy of cancer using temozolomide and interferon alpha 2b. The concentration of temozolomide ranges from 50-400 mg/m² with a daily dose administered over a 2-10 day period and can be administered in repeated cycles of 28-42 days. The concentration of interferon alpha 2b ranges from 1 million to 25 million IU per m². (see pages 3-5).

The only differences between the instant invention and the reference is the use of PEG₁₂₀₀₀-interferon alpha 2b, the specific concentrations of PEG₁₂₀₀₀-interferon alpha 2b and the formation of a kit.

Ragab discloses a dosing cycle of temozolomide of daily administrations for 5-25 days (at 40-150mg/m²/day) followed by a rest period of 4-15 days (abstract).

Kline discloses at PEG stabilizes interferon alpha during lyophilization and specifically exemplifies PEG 12000 and interferon alpha 2b (see entire reference).

WO 95/13090 discloses the formation of long-acting alpha interferon compositions using PEG and specifically discloses the use of using PEG with a MW ranging from 2000-12,500 (see page 6, lines 18-21 and page 2, lines 25+).

Thus, in view of the fact that PEG 12000 stabilizes interferon alpha 2b during lyophilization and that PEG in the range of 2000-12500 creates a long-acting alpha interferon, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use interferon alpha 2b linked to PEG 12000 to form a more stable, long-acting interferon alpha 2b. The formation of a kit using known components is within the purview of one skilled in the art. Furthermore, the dosing cycle of temozolomide of daily administrations for 5-25 days (at 40-150mg/m²/day) followed by a rest period of 4-15 days is obvious in view of Ragab. Further optimization of dosages and dosing regimes is within the purview of one skilled in the art.

(11) Response to Argument

Appellant argues each reference individually and does not address the motivation for combining the references. In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, appellant argues that the primary references teaches away from appellant's invention because it does not use pegylated interferon alpha. It is true that the primary reference does not teach pegylated

interferon, if it did, then the rejection would be under 35 USC 102. This reference does not teach away from appellant's invention because the reference does not say one should not use pegylated interferon.

Appellant argues that the claimed method has a "synergistic advantage" and refers to pages 8-23 of the specification. A synergistic effect is shown by showing the effects of one component and then the other and then the combination of the two. The specification at the cited pages does not do this and thus there is no objective evidence that the claimed method has a synergistic advantage.

Appellant argues that the Examiner uses hindsight and that the Examiner has not provided any motivation. The motivation comes from the secondary references (as is clearly discussed in the rejection). Since the references, when combined, make appellant's invention obvious, it is clear that there is no hindsight.

For the above reasons, it is believed that the rejections should be sustained.

Application/Control Number: 09/767,424
Art Unit: 1642


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Respectfully submitted,

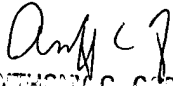
Sheela J Huff
Primary Examiner
Art Unit 1642

SJH
November 4, 2003

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